K122401

SunTech Medical®

SunTech Medical, Inc.
Special 510(k) Submission
Tango M2
510(k) Summary

NOV 2 2012

(1) Submitter information

Name:	SunTech Medical, Inc
Address:	507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200
Telephone:	919.654.2334
FAX:	919.654.2301
Contact person:	Chuck Setzer (Official Correspondent). SunTech Medical 507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200 Tel: 919-654-2334 Fax: 919-654-2301
Date prepared:	02AUG2012

(2) Name of Device

Trade Name:	Tango M2 Blood Pressure Monitor
Common Name:	Noninvasive blood pressure measurement system
Classification name:	System, Measurement, Blood Pressure, Non-Invasive, DXN 870.1130 Oximeter, DQA, 870.2700

(3) Legally-marketed predicate devices

The Tango M2 is a modification of the Tango+ Blood Pressure Monitor, K053209 and Tango Blood Pressure Monitor, K970629.

The Tango M2 is substantially equivilent to these devices.

(4) Description

The Tango M2, a microprocessor based blood pressure monitor and oxygen saturation measurement system intended to be used with stress-test systems, uses Korotkoff sounds to determine blood pressure and an optical finger sensor for oxygen saturation. An internal electric pump is used to inflate the cuff, and deflation is controlled by two valves. Tango M2 has the ability to make blood pressure and saturation measurements at predetermined intervals (normally from a schedule determined by the physician), or on

demand. Additionally, the TangoM2 has the ability to make an Oscillometric blood pressure determination at the command of the operator while the patient is stationary.

(5) Intended Use

Tango M2 is a non-invasive blood pressure monitor, with the optional capability to monitor oxygen saturation (SpO_2), for use in cardiac or exercise stress testing. It measures and displays a patient's systolic and diastolic blood pressure, and with the SpO_2 option, percent oxygen saturation of arterial blood.
Use Tango M2 only with adult patients, while they undergo cardiac or exercise stress test under the supervision of a physician.

The intended use of the Tango M2, as described in its labeling, has not changed as a result of the modifications to the original device.

(6) Comparison to Predicate Devices

The device has the same basic construction as the predicate devices. Both modified and original devices share the same specifications, measurement ranges, and intended uses. The devices are manufactured from the same types of materials using the same production methods and are intended for the same patient populations.

(7) Testing and Validations

The Tango M2 has been tested to the applicable requirements of the following standards and requirements documents. These tests have indicated passing results.

- IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

(8) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, SunTech Medical concludes that the Tango M2 is safe, effective and substantially equivalent to the predicate devices described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

SunTech Medical, Inc.
c/o Mr. Chuck Setzer
507 Airport Blvd, Suite 117
Morrisville, NC 27560

NOV 2 2012

Re: K122401
Trade/Device Name: Tango M2 Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: October 3, 2012
Received: October 4, 2012

Dear Mr. Setzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K122401

Device Name: Tango M2 Noninvasive Blood Pressure Monitor

Indications for Use:

The SunTech Medical Tango M2 NIBP monitor with optional Pulse Oximeter is indicated for use in measuring and displaying blood pressure, heart rate, functional oxygen saturation of arterial hemoglobin (SpO_2) of adult patients in hospitals, medical facilities, and subacute environments.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122401